EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S, Plaintiff, v. SANOFI-AVENTIS, AVENTIS PHARMACEUTICALS INC., and AVENTIS PHARMA DEUTSCHLAND GMBH, Defendants.	)	C.A. No. 05-645-SLR

DEFENDANTS' CONSOLIDATED AND AMENDED ANSWER AND COUNTERCLAIMS

Aventis Pharmaceuticals Inc., sanofi-aventis, and Aventis Pharma Deutschland GmbH (herein sometimes referred to collectively as "Aventis") hereby consolidate and amend their previous answers and counterclaims (D.I. 8, 16) as follows. As a general and preliminary matter, Aventis notes that the Complaint retains references to Aventis Pharma AG, an entity that was dismissed from this action by Novo's Notice of Dismissal, filed December 2, 2005 (D.I. 14). Accordingly, Aventis hereby answers only on behalf of Aventis Pharmaceuticals, Inc., sanofi-aventis and Aventis Pharma Deutschland GmbH.[1] Aventis generally denies as improper any and all allegations in the Complaint that refer to Aventis Pharma AG, and nothing herein shall constitute or be construed as any admission, acknowledgement or waiver by Aventis Pharma AG.

[1] While the Complaint names Aventis Pharma Deutschland GmbH, this entity is now known as sanofi-aventis Deutschland GmbH. Accordingly, this current title will be used in this First Amended Answer.

THE PARTIES

1. Aventis is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint and therefore denies each and every allegation contained in paragraph 1 of the Complaint.

2. No response is necessary, as paragraph 2 of the Complaint does not concern Aventis.

3. Aventis denies the allegations set forth in paragraph 3 of the Complaint, except admits that sanofi-aventis S.A. is a corporation organized and existing under the laws of France, having a place of business at 174/180 Avenue de France, Paris, Cedex 75013 France.

4. Aventis denies the allegations set forth in paragraph 4 of the Complaint, except admits that Aventis Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Somerset Corporate Blvd., Bridgewater, New Jersey 08807, and admits that Aventis Pharmaceuticals, Inc. is related to sanofi-aventis S.A.

5. Aventis denies the allegations set forth in paragraph 5 of the Complaint, except admits that sanofi-aventis Deutschland GmbH has a place of business at Industriepark Hoechst, D – 65926 Frankfurt am Main, Germany, and admits that sanofi-aventis Deutschland GmbH is related to sanofi-aventis S.A.

6. As set forth above, Aventis Pharma AG is no longer a defendant in this litigation. Accordingly, Aventis denies the allegations set forth in paragraph 6 of the Complaint as irrelevant and improper.

7. Aventis denies the allegations set forth in paragraph 7 of the Complaint.

8. No response is necessary as paragraph 8 of the complaint does not concern Aventis.

JURISDICTION AND VENUE

9. Aventis admits that Novo styled its cause of action as one for patent infringement under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. §§ 271 and 281-285.

10. Aventis admits that 28 U.S.C. §§ 1331 and 1338(a) give this Court subject matter jurisdiction over actions arising under the patent laws of the United States, Title 35, United States Code, and Aventis does not contest this Court's subject-matter jurisdiction under the provisions of 28 U.S.C. §§ 1331 and 1338(a) for purposes of this action only.

11. Aventis admits that Aventis Pharmaceuticals, Inc. sells various products and does business throughout the United States and in this District. Aventis otherwise denies the allegations contained in paragraph 11 of the Complaint.

12. Aventis admits that Aventis Pharmaceuticals, Inc. distributes medical devices that are distributed and used throughout the United States, including in this District. Aventis otherwise denies the allegations contained in paragraph 12 of the Complaint.

13. Aventis admits that Aventis Pharmaceuticals, Inc. was served in accordance with 8 Del.C. § 321, and Aventis Pharmaceuticals, Inc., sanofi-aventis S.A., and sanofi-aventis Deutschland GmbH do not contest the personal jurisdiction of this Court in this proceeding. Aventis denies that defendants have committed acts of infringement in Delaware and therefore denies the remaining allegations in paragraph 13 of the Complaint.

14. Aventis admits that venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(c) and 1400(b), although Aventis does not admit that this forum is the most convenient

forum under 28 U.S.C. § 1404, and denies the remaining allegations set forth in paragraph 14 of the Complaint.

FACTS

15. Aventis admits that Exhibit A to the Complaint purports to be a copy of United States Patent No. 6,582,408 ("the '408 patent"), entitled MEDICAL DEVICE, and appears to have been issued by the United States Patent and Trademark Office ("USPTO") on June 24, 2003. Aventis, however, denies that the USPTO duly and legally issued the '408 patent, and denies all other allegations of paragraph 15 of the Complaint.

16. Aventis lacks sufficient knowledge to form a belief as to the allegations of paragraph 16 of the Complaint and therefore denies them.

COUNT I

17. Aventis denies that defendants are directly infringing any of the claims of the '408 patent or contributing to or actively inducing infringement of any of the claims of the '408 patent by others. Aventis otherwise denies the allegations set forth in paragraph 17 of the Complaint.

18. Aventis denies that defendants are infringing the '408 patent and otherwise denies all other allegations set forth in paragraph 18 of the Complaint.

19. Aventis denies that defendants are infringing the '408 patent and otherwise denies all other allegations set forth in paragraph 19 of the Complaint.

20. Aventis denies that defendants are infringing the '408 patent and otherwise denies all other allegations set forth in paragraph 20 of the Complaint.

21. Aventis denies the allegations set forth in paragraph 21 of the Complaint.

AFFIRMATIVE DEFENSES

1. Aventis incorporates by reference the responses and denials set forth in paragraphs 1 through 21.

2. Aventis has not infringed and does not infringe the '408 patent.

3. Aventis has not induced and does not induce infringement of the '408 patent.

4. Aventis has not contributed and does not contribute to the infringement of the '408 patent.

5. The claims of the '408 patent are invalid under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112.

6. The '408 patent is unenforceable due to Novo's inequitable conduct during prosecution of the application that issued as the '408 patent.

COUNTERCLAIMS

Aventis, for its counterclaims against Novo, alleges the following:

PARTIES

1. Aventis Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Sanofi-aventis S.A. is a corporation organized and existing under the laws of France, having a place of business at 174/180 Avenue de France, Paris, Cedex 75013 France. Sanofi-aventis Deutschland GmbH is a corporation organized and existing under the laws of Germany, having a place of business at Industriepark Hoechst, D – 65926 Frankfurt am Main, Germany.

2. Upon information and belief, Novo Nordisk A/S ("Novo") is a corporation organized and existing under the laws of Denmark, with offices located in Novo Allé, 2880 Bagsværd, Denmark.

JURISDICTION AND VENUE

3. Aventis's counterclaims against Novo arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, and under the Patent Laws of the United States, Title 35 United States Code. Accordingly, this Court has original and pendant subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

4. Venue in this judicial district is proper under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

FIRST COUNTERCLAIM COUNT: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '408 PATENT

5. Aventis incorporates by reference and realleges the allegations of counterclaim paragraphs 1 through 4, the defenses of affirmative defense paragraphs 1 through 6, and the responses and denials set forth in paragraphs 1 through 21.

6. Novo alleges in its Complaint that it owns the '408 patent and that Aventis infringes the '408 patent.

7. The pending litigation and disputes between Aventis and Novo establish an existing and actual case or controversy between them regarding whether Aventis infringes the '408 patent.

8. The manufacture, assembly, use, offer to sell, sale, distribution, or importation into the United States of the Aventis OptiClik™ device does not infringe and has not infringed the '408 patent, either literally or under the doctrine of equivalents.

9. Aventis does not infringe and has not infringed the '408 patent, either literally or under the doctrine of equivalents.

10. Aventis does not induce and has not induced infringement of the '408 patent.

11. Aventis does not contribute and has not contributed to the infringement of the '408 patent.

SECOND COUNTERCLAIM COUNT: DECLARATORY JUDGEMENT OF INVALIDITY OF THE '408 PATENT

12. Aventis incorporates by reference and realleges the allegations of counterclaim paragraphs 1 through 11, the defenses of affirmative defense paragraphs 1 through 6, and the responses and denials set forth in paragraphs 1 through 21.

13. The pending litigation and disputes between Aventis and Novo establish an existing and actual case or controversy between them regarding whether the '408 patent is invalid.

14. The claims of the '408 patent are invalid under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including, but not limited to, 35 U.S.C. § 102, 103, and/or 112.

THIRD COUNTERCLAIM COUNT: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '408 PATENT

15. Aventis incorporates by reference and realleges the allegations of counterclaim paragraphs 1 through 11, the defenses of affirmative defense paragraphs 1 through 6, and the responses and denials set forth in paragraphs 1 through 21.

16. The pending litigation and disputes between Aventis and Novo establish an existing and actual case or controversy between them regarding whether the '408 patent is unenforceable.

17. The '408 patent is unenforceable as a result of Novo committing inequitable conduct in the Patent Office during prosecution of the application that issued as the '408 patent. Specifically, Novo failed to provide the examiner with material references, of which Novo was undoubtedly aware, as the references are Novo patents that disclose snap-lock arrangements in pen-type injector devices. Novo knew or should have known that the withheld references were highly material to the patentability of the pending claims of '408 patent, yet still withheld those references from the examiner.

18. Novo argued during prosecution of the application that issued as the '408 patent that rotation of the main parts of the injector, *i.e.*, the cartridge assembly and the dosing assembly, could cause axial movement of the cartridge assembly relative to the dosing assembly. This axial movement would then result in the displacement of the plunger means from the stopper of the cartridge, causing an inaccurate dose. Therefore, Novo argued, it was necessary to select couplings between the cartridge assembly and dosing assembly, and between the cartridge assembly and the needle assembly, that would prevent this rotation and the resulting displacement. During the course of prosecution, all claims of the '408 patent were amended to recite that one of these couplings was a "snap-lock".

19. Novo withheld three principal references from the examiner, United States Patent Nos. 6,004,297 ("the '297 patent"), 5,968,021 ("the '021 patent") and 5,331,954 ("the '954 patent"). Each of these references disclosed a pen-type injector that included a snap-lock coupling chosen to prevent the very type of rotation Novo argued was a problem in the '408 prosecution. These three withheld references are discussed in turn below.

20. The application that issued as the '297 patent was filed January 28, 1999 claiming priority to a provisional application filed February 5, 1998. Accordingly, the '297

patent is prior art to the '408 patent under 35 U.S.C. § 102(e). The applications for the '297 patent and the '408 patent were co-pending in the Patent Office for a short time and the '297 patent issued some 3 1/2 years before the '408 patent was issued, more than enough time to bring it to the attention of the patent examiner. The '297 patent is assigned to Novo Nordisk A/S.

21. The '297 patent is entitled "Injection Syringe" and discloses a pen-type injector of the same sort disclosed and claimed by the '408 patent. Additionally, the injector of the '297 patent includes a snap-lock coupling between the housing and the cartridge assembly:

> The syringe comprise [*sic*] a tubular housing **1** which is by a partition **15** divided into a first and a second division into the first one of which an ampoule holder **2** is snapped by a snap-lock comprising a ring shaped bead **3** on the ampoule holder **2** which bead is snapped into a corresponding circumferantial [*sic*] groove in the inner wall of the housing **1** near an open end thereof. By this snap connection the ampoule holder **2** is secured in the housing so that it can be rotated but not axially displaced relative to this housing. ('297 patent, col. 5, lines 35-43).

22. Accordingly, the '297 patent discloses the very snap-lock coupling arrangement designed to prevent axial movement of the cartridge (ampoule) relative to the dosing assembly as that disclosed and claimed by the '408 patent. A reasonable examiner would have found this disclosure pertinent to patentability of the "invention" of the '408 patent and therefore, the '297 patent is a highly material reference with respect to the '408 patent. It cannot be said to be cumulative of other art before the examiner because the examiner did not consider any art disclosing such a use of a snap-lock fitting. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose a snap-lock coupling.

23. The application that issued as the '021 patent was filed as a PCT application on February 27, 1995 and the application was given a 35 U.S.C. § 102(e) date of August 22, 1996. The '021 patent issued on October 19, 1999, some 9 months before the application for the '408 patent was filed.

24. The '021 patent is entitled "Magazine and Removable Needle Unit" and discloses a needle unit having a "sleeve designed to be snap-locked onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging a circumferential recess in the outer wall of the connecting piece." ('021 patent, Abstract). The summary of the invention states that "[t]he object of the invention is to provide a needle unit of the snap-on type, which may easily be snapped onto a durable pen-type syringe and which may easily be dismounted from the syringe to make it possible to change the needle without having to dispose of the syringe." ('021 patent, col. 1, lines 46-50). Thus, the '021 patent describes a snap-lock coupling for attaching a needle to the cartridge assembly of a pen-type injector device, exactly a claimed by the '408 patent. A reasonable examiner would have found this disclosure pertinent to patentability of the "invention" of the '408 patent, therefore the '021 patent is a highly material reference with respect to the '408 patent. It cannot be said to be cumulative of other art before the examiner because the examiner did not consider any art disclosing such a use of a snap-lock fitting. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose a snap-lock coupling.

25. The '954 patent issued July 26, 1994, some 5 years before the application for the '408 patent was filed, and accordingly is prior art to the '408 patent. The '954 patent is entitled "Device for Delivery of Nasal Liquids" and discloses a pen-shaped device for nasal

administration of a liquid medicine. Essentially, it is pen-type injector without a needle. The device of the '954 patent includes first and second housing elements "coupled together to allow rotation but no axial displacement of the first housing element with respect to the second housing element" ('954 patent, col. 1, lines 53-56). The first housing element carries a cartridge of medication, analogous to the cartridge assembly of the '408 patent, while the second housing element contains dosing and delivery mechanics, analogous to the dosing assembly of the '408 patent. ('954 patent, col. 1, line 56 to col. 2, line 13). The coupling between the housing elements is further described as follows:

> FIG. 1 shows a pen shaped device having a first housing element **1** and a second housing element **2** snapped together by an external bead **3**, and the first housing element **1** being snapped into an annular groove **4** in the second housing element **2** permitting the two housing elements to be rotated in relation to each other about the common length axis, but not to be displaced in relation to each along this axis. ('954 patent, col. 4, lines 3-10).

26. The '954 patent thus discloses exactly the snap-lock coupling between the cartridge assembly and the dosing assembly as the disclosed and claimed by the '408 patent. A reasonable examiner would have found this disclosure pertinent to patentability of the "invention" of the '408 patent, therefore the '954 patent is a highly material reference with respect to the '408 patent. It cannot be said to be cumulative of other art before the examiner because the examiner did not consider any art disclosing such a use of a snap-lock fitting. Indeed, in a Statement of Reasons for Allowance, the examiner explained that he was allowing the claims because the prior art of record did not disclose a snap-lock coupling.

27. The same Novo in-house attorneys who were involved in the prosecution of the '408 patent also were involved in the prosecution of the three withheld references. Accordingly, Novo undeniably knew of the withheld references during prosecution of the application that issued as the '408 patent, yet withheld those references from the patent

examiner. Given the high degree of materiality of each of these references, not to mention the materiality of all three taken together, there can be no question that the references were withheld deliberately and with intent to deceive the Patent Office. It is beyond the bounds of credibility to argue that Novo innocently failed to cite to the examiner three of its own patents that disclose snap-lock couplings, particularly in view of the examiner's Statement of Reasons for Allowance stressing the importance of the snap-lock coupling to patentability of the claims of the '408 patent. Accordingly, one must conclude that, in the totality of the circumstances, Novo's withholding of the references was deliberate and with the requisite intent to justify a finding of inequitable conduct and a declaration that the '408 patent is unenforceable.

RELIEF REQUESTED

WHEREFORE, Defendant respectively requests that this Court:

(A) Dismiss with prejudice the Complaint of Novo and deny all of Novo's requests for relief;

(B) Declare the '408 patent not infringed;

(C) Declare the '408 patent invalid;

(D) Declare the '408 patent unenforceable;

(E) Enter a permanent injunction enjoining Novo from asserting or otherwise seeking to enforce the '408 patent against sanofi-aventis S.A., Aventis Pharmaceuticals Inc., sanofi-aventis Deutschland GmbH, or any of their customers;

(F) Declare this case exceptional under 35 U.S.C. § 285;

(G) Award Aventis its costs, disbursements, and reasonable attorney fees (including expert fees) incurred in this action; and

(H) Enter such other and further relief as the Court deems just and proper.

ASHBY & GEDDES

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